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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,343	12/17/2004	Heinz Von Der Kammer	P67751US1	4112
136 7590 07/28/2008 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004				
EXAMINER STANDLEY, STEVEN H				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,343

Applicant(s)

VON DER KAMMER ET AL.

Examiner

STEVEN H. STANDLEY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 21-35 is/are pending in the application.
4a) Of the above claim(s) 1-17 and 21-30 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 31-35 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 4/09/08 has been made of record. Claims 1-17 and 21-35 are pending. Claims 18-20 (under review) have been cancelled. New claims directed to the subject matter of claims 18-20, claims 31-35, have been added by Applicant. Claims 1-17 and 21-30 remain withdrawn as directed to a non-elected invention.

Objections/Rejections: Withdrawn

Claim Rejections - 35 USC § 102

2. Rejection of claim 18 under 35 USC § 102(b) over Donello et al is withdrawn due to applicant's amendment to cancel the claim. A glutamic acid free of any covalent linkage to another amino acid(s) of Maguin-1 or 2 would not reasonably be construed as "a translation product" of Maguin-1 or 2.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. New claim 31 is rejected under 35 USC 112, 1st paragraph, scope of enablement. The basis for this rejection is set forth for cancelled claim 18 in the office action dated 10/09/07. The claim is enabled for an assay for screening candidate compounds for neurodegenerative diseases (in particular Alzheimer's), but not for an assay that positively identifies compounds that are "modulators of neurodegenerative disease." Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that adding the word 'candidate' to the preamble obviates the rejection. This is not found persuasive because the claim recites positively determining that the compound is a modulator of Alzheimer's Disease (AD) in the last two lines of the claim. Therefore as recited the claimed method is still to identifying compounds that modulate AD solely based on the assay itself, which lacks enablement. See the prior action of 10/09/07.

4. Claims 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The basis for this rejection is set forth for claims 18-22 at pages 4-6 of the previous Office Action dated 10/09/07. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues on the bottom of page 16 and top of page 17 of Remarks (4/09/08) that the claims are limited to the DNA encoding the proteins, the RNA encoding the proteins and the proteins of MAGUIN-1 and 2. This is not found persuasive because the claims actually recite "a gene encoding..." and "a transcription product..." and "a translation product..." The examiner construes the indefinite articles to indicate that it is ANY

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product within the above. This includes fragments of "MAGUIN" (SEQ ID NO: 1-2), and DNA and mRNA encoding it. While the sequences are known, it is not known or disclosed by the specification or the prior art what part of any of the foregoing products can be measured to adequately determine if the test compound would be a candidate for modulating AD. Additionally, there is no written description as to what constitutes the "activity" and "ligand" in the claimed methods. For "activity", the specification only discloses that this is a measure for the ability of a transcription or translation product to produce a biological effect or measure for a level of biologically active molecules (page 6, lines 19-21). There is no description in the instant application of a ligand to be utilized in the claimed methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 31-35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then

narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 31-35 recite the broad recitations "MAGUIN-1" and "MAGUIN-2", and the claims also recite (SEQ ID NO: 1) and (SEQ ID NO: 2) which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 34 is rejected under 35 U.S.C. 102(b) are being anticipated by Yao et al (1999). The basis for this rejection is set forth for claim 20 for the reasons made of record in the office action dated 10/09/07. Applicant's arguments have been fully considered and not found to be persuasive. Applicant admits firstly on page 19 of Remarks dated 4/09/08 that Yao disclose C-terminal fragments of Maguin 1 and 2, but then argues that it does not meet the limitation "Maguin-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)." This is not found persuasive because the steps do not

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require using full-length Maguin-1 or 2 and the method is positively accomplished by Yao et al by using the c-termini of Maguin-1 and 2. See the rejection of 10/09/07 page 7-8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yao et al. (1999) in view of Tao et al. The basis for the rejection of claim 32 under 35 USC § 103(a) is set forth for claims 18-20 at pages 8-10 of the office action dated 10/09/07. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues on page 20 of Remarks dated 4/09/08 that the amendments overcome the rejection because the art does not teach "Maguin-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)," or the gene or the RNA or the translation product. This is not found persuasive because Yao et al. clearly teaches "a translation product [ie, a large piece of the c-terminus]" of Maguin-1 and 2 and that is all that is required. Yao et al. also teach the Maguin-1 and 2 ligand psd-95 protein-protein interaction of claims 32 and 34.

Tao et al disclose an assay to identify compounds that interfere with the binding of NMDA receptor c-terminus and the PDZ domains of PSD-95, and with nNOS and the PDZ domains of PSD-95. Moreover, Tao et al disclose a preferable method of identifying compounds that bind the PDZ domains of PSD-95 and inhibit binding of NMDA receptors or nNOS (see [0026]). Thus, Tao teaches all the steps of claim 32. In particular, see section 0016.. Tao et al. also disclose contacting a cell with a test compound (psd-95 antisense polynucleotides; see example 2, page 5) and measuring the expression of PSD-95.

Maguin-1 and 2 bind at the same place in PSD-95 that NMDA receptors bind. Thus, one would clearly be motivated to combine the two references and perform methods of identifying compounds that disrupt the binding between Maguin-1 (or NMDA) with PSD95 or change the expression of Maguin-1 because both assays identify compounds that would likely be useful in treating pain, for instance. See Tao et al. Abstract, wherein it is disclosed that displacing NMDA from PSD-95 results in anesthesia.

8. Claims 33, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yao et al. in view of Tao et al. as applied to claim 32 above, and further in view of Ruehr et al. (1999).

Yao et al. teach as described above.

Yao et al. does not teach an assay of expression of Maguin as useful or a fluorescence assay of protein-protein interactions.

Tao et al. teaches NMDA receptors bind the same place that Maguin-1 and 2 do and teach an assay to identify compounds that change expression of proteins that interfere with PSD-95-NMDA/Maguin-1, 2 interaction.

Tao et al. does not teach a fluorescence assay of protein-protein interactions.

Rhuer et al. teach measuring the fluorescence (fluorescent resonance energy transfer; FRET) as an indication of whether PKA regulatory protein and an anchoring protein directly interact (see abstract, figure 5 on page 33095).

One of ordinary skill in the art would be motivated to combine the teachings of Yao et al. with Tao et al and Rhuer et al. because the method effectively determines if two molecules are interacting (see discussion, page 33095).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Stucker can be reached on (571) 272-0911.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
7/09/08

/Bridget E Bunner/
Primary Examiner, Art Unit 1647